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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,374	01/12/2001	Robin James Spivey	R&G C- 317	1252

7590 03/11/2003

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
1641	11

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/760,374	SPIVEY ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Kartic Padmanabhan	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 23 December 2002 .

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-17 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 12 January 2001 is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .  
4)  Interview Summary (PTO-413) Paper No(s) .  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: .

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I in Paper No. 10 is acknowledged.

### ***Priority***

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

3. The information disclosure statement filed 6/21/01 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Therefore, EP 0 073 980 has not been considered.

### ***Specification***

4. Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and ***generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words.*** It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 recites the limitations "the lines" in line 2, "the intensity" in line 8, and "the output" in line 11. There is insufficient antecedent basis for these limitations in the claim.

8. Claim 6 recites the limitation "said comparison" in line 6 of the claim. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 14 recites the limitations "the result" in line 13, "the amount" in line 14, and "the intensity" in line 18. There is insufficient antecedent basis for these limitations in the claim.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (US Pat. 5,580,794) in view of Ivarsson et al. (US Pat. 5,313,264).

Allen teaches a disposable electronic assay device comprising a housing, a sample receptor means for receiving a sample with analyte, sample treatment means for reacting the sample with a reagent to produce a physically detectable change, detector means that produces an electrical signal indicative of analyte presence, processing means that stores assay calibration information, wherein the processing means calibrates the sample treatment and detector means using the stored information, the processor means further converting the electrical signal to a digital output, and display means for visually displaying the digital output. The processing means of the reference further calibrates the detector means to a reference standard using the stored calibration information and compares the stored calibration information to the electrical signal to determine assay accuracy. The processing means may also include a timer that measures the shelf life of the device. The device of the reference also comprises a light emitting diode as the light source for illuminating the detection zones of the reference (Cols. 29-31). The

physically detectable change may be a change in the reflectivity or transmission of an output surface. The signal processing means may include an analog to digital conversion means. The sample treatment means can include separation means for separating interfering substances, as well as sample development means (Col. 4). The device of the reference has the ability to auto read for sample presence at a specific time interval after sample application. The display may comprise a liquid crystal (Col. 7). The processor of the reference also serves to control any time delays during reading, and determines when the reaction has stabilized and concluded (Col. 12). The device of the reference can be used to detect various analytes in a number of different samples, including saliva. However, the reference does not teach the use of a photodetector array, nor does it teach the use of control and background zones.

Ivarsson et al. teach an optical biosensor system, wherein a photodetector comprising an array of individual photodetectors is used (abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the array of photodetectors of Ivarsson et al. with the device and method of Allen because a photodetector array allows for the detection of light from multiple sensing surfaces simultaneously. In addition, although the references do not teach the use of background or control zones, inclusion of such zones with the modified device of Allen and Ivarsson simply represent an optimization of the device and method, as one would have had a reasonable expectation of success in including these zones to eliminate the possibility of any interference or contamination with the assay results. Further, it would have been obvious to use the processor to segment the data for easier comparison and to determine if the test zones produced a signal indicative of analyte presence above the background. Finally, the selection of specific detectors, such as a CCD, and digitizers, as well as the inclusion of a filter simply represent optimizations

of the device and method of Allen and Ivarsson et al., and one of skill could have used a filter, if necessary, to obtain a better signal, and selected any detector and digitizer desired with a reasonable expectation of success.

***Conclusion***

Claims 1-17 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan  
Patent Examiner  
Art Unit 1641

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March 10, 2003



LONG V. LE  
SUPPLEMENTARY PATENT EXAMINER  
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03/10/03